Product Description

The PureGraft™ 250/PURE System is a novel technology that utilizes an advanced lipofiltration system to streamline the graft preparation process by selectively washing lipoaspirate while draining any unwanted tumescent fluid, free lipid and debris. The system can prepare 50 – 250 mL of graft in a closed, sterile environment in less than 15 minutes, and allows for user defined hydration levels of the final graft.

Indications For Use:

The Cytori PureGraft 250/PURE System is indicated for use in the harvesting, filtering and transferring of autologous fat tissue for reinjecting back into the same patient for Autologous Fat Transfer (AFT) procedure.

The PureGraft™ 250/PURE System includes:

A. PureGraft™ 250 / QTY. 1  
B. 1.5 L Waste Bag / QTY. 1  
C. Inlet Tubing Set / QTY. 1

For optimal performance, the PureGraft™ 250/PURE System should be used in conjunction with the PureGraft™ 550/IS Instrument Set. This Set is composed of the following reusable, autoclavable components:

D. Tissue Access Port Adapter (TAPA) / QTY. 12  
E. TAPA-to-Luer Adapter / QTY. 2

F. PureGraft™ Easel / QTY. 1  
G. PureGraft™ Slider / QTY. 1

The PureGraft™ Easel was designed as a stand to hold the PureGraft™ 250 for optimal fluid flow and the PureGraft™ Slider facilitates the movement of excess fluids away from the tissue and into the Waste Bag while guiding the tissue towards the Tissue Access Port for graft extraction. For storage, sterilization, and proper instructions for usage of these products, see the separate Instructions for Use included in the product packaging of the PureGraft™ 550/IS Instrument Set.
**STEP 1  SET-UP**

A. Place autoclaved PureGraft™ Easel and Slider on sterile field. The Easel should be placed in an upright position.

*Note:* The PureGraft™ Easel can be positioned on sterile field separately using the 3 adjustable legs located behind the front plate, or fitted onto the autoclave tray included with the Cytori® 540/IS Graft Delivery Instrument Set.

B. Open Tyvek pouches containing the PureGraft™ 250/PURE System components, and hang the PureGraft™ 250 on the Easel. Slide clamp on drain line near the PureGraft™ 250 before placing the 1.5 L Waste Bag well below the level of the PureGraft™ 250. Ensure the clamp is in the **OPEN** position.
**STEP 2 TISSUE ADDITION**

The PureGraft™ System is now ready to process fat tissue.

**A.** Aseptically collect adipose tissue for graft into 60 mL Toomey syringes. Open the Tyvek pouch containing the Tissue Access Port Adapters (TAPA) and TAPA-to-Luer Adapters. Place one TAPA on each Toomey Syringe containing harvested fat tissue.

**Note:** 12 TAPAs are provided.

**B.** Attach the tissue-filled syringe to the PureGraft™ 250 by placing the male portion of the TAPA into the port labeled “Tissue” and push the syringe plunger to empty the syringe contents into the PureGraft™ 250. Repeat until the total desired graft volume between 50-250 mL of tissue is introduced into the PureGraft™ 250. Ensure excess fluid is draining into the Waste Bag.

**Note:** Insert 30-50% more tissue than desired graft volume to allow for drainage of excess fluids within the graft material.

<table>
<thead>
<tr>
<th>Tissue Volume (mL)</th>
<th>Anticipated Graft Material (mL)</th>
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</thead>
<tbody>
<tr>
<td>50</td>
<td>25-35</td>
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<tr>
<td>100</td>
<td>50-70</td>
</tr>
<tr>
<td>150</td>
<td>75-105</td>
</tr>
<tr>
<td>200</td>
<td>100-140</td>
</tr>
<tr>
<td>250</td>
<td>125-175</td>
</tr>
</tbody>
</table>
**Step 3** Tissue Washing

**A.** **Close** the pinch clamp to the 1.5 L Waste Bag. If using syringe method for adding wash solution, draw Lactated Ringer’s (LR) Solution from sterile bowl into a 60 mL luer lock syringe and connect to the “Inlet” port on the PureGraft™ 250.

Reference the table below for amount of wash solution to be added relative to tissue.

<table>
<thead>
<tr>
<th>Tissue Volume (mL)</th>
<th>LR Solution (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>100</td>
<td>100</td>
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<tr>
<td>150</td>
<td>150</td>
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<tr>
<td>200</td>
<td>150</td>
</tr>
<tr>
<td>250</td>
<td>150</td>
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Alternate Tissue Washing Method

Instead of using the syringe method, LR Solution can be added to the PureGraft™ 250 by using the Inlet Tubing Set contained in the PureGraft™ 250/PURE System. **Close** the pinch clamp to the Inlet Tubing Set and spike the IV bag. **Open** pinch clamp to the Inlet Tubing Set to prime the IV line and then **close**. Connect the male luer end of the Inlet Tubing Set to the center port marked “Inlet” of the PureGraft™ 250. **Open** pinch clamp to the Inlet Tubing Set to add LR Solution.
B. Agitate the tissue-filled PureGraft™ 250 manually for approximately 15 seconds ensuring that all corners of the device are accessed.

C. **OPEN** pinch clamp on 1.5 L Waste Bag and allow fluid to drain from the PureGraft™ 250 into the Waste Bag for approximately 3 minutes, then **CLOSE** pinch clamp.

D. Wash tissue twice using preferred method (Syringe or Inlet Tubing Set), and **OPEN** pinch clamp on Waste Bag to drain excess rinse fluid for 1-5 minutes depending on preferred graft hydration level.
**STEP 4 GRAFT EXTRACTION**

A. Use PureGraft™ Slider to guide tissue towards the Tissue Access Port, while simultaneously filtering any remaining excess fluid into the Waste Bag. Then **CLOSE** pinch clamp to the Waste Bag.

B. Aseptically attach a TAPA to an empty Toomey syringe and connect to the PureGraft™ 250 by placing the male portion of the TAPA into the port labeled “Tissue”.

C. Extract graft from the PureGraft™ 250 by slowly pulling the syringe plunger until syringe is filled. Use the PureGraft™ Slider as needed to extract the maximum amount of graft from the PureGraft™ 250.

D. Attach TAPA-to-Luer adapter to the end of TAPA on the filled syringe. Then load luer-lock syringe onto the blue end of TAPA-to-Luer adapter to prepare for reinjection.

E. Once tissue is removed from the device, properly dispose of all disposable components using Universal Precautions for Blood-borne Pathogens.
CAUTION: Any use of the PureGraft™ System or its output is at the sole discretion and clinical judgment of the treating physician. Cytori Therapeutics does not practice medicine or provide medical services or advice, and all information herein has been prepared for informational and illustrative purposes only.

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